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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,875	06/21/2006	Ahmed Sheriff	P71167US0	3644
136 7590 09/26/2008 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004				
EXAMINER				
WEN, SHARON X				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
09/26/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/572,875

**Applicant(s)**

SHERIFF ET AL.

**Examiner**

SHARON WEN

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-33 and 35-55 is/are pending in the application.
- 4a) Of the above claim(s) 38, 39, 41-45 and 47-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-33, 35-37 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment, filed 05/08/2008, has been entered.

Claims 1-26, 34, 46 and 56-58 have been canceled.

Claims 27-33, 35-46 and 47-55 are pending.

Claims 38-39, 41-45 and 47-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic claim.

Claims 27-33, 35-37 and 40 are currently under examination as they read an antibody which binds or inhibits secretory phospholipase A2 IIA (sPLA2 IIA) and a pharmaceutical composition or a medicament comprising the compound.

2. This Action will be in response to Applicant's Arguments/Remarks, filed 04/18/2008.

The rejections of record can be found in the previous Office Action.

### ***Specification***

3. The previous objection to the specification for failing to provide proper antecedent basis for the claimed subject matter for the claimed limitation of "humanized immune system" has been withdrawn in view of Applicant's cancellation of the claim in the amendment, filed 05/08/2008.

### ***Claim Rejections - 35 USC § 112 second paragraph***

4. The previous rejection under 35 U.S.C. 112, second paragraph for the recitation "a humanized (with a humanized immune system) vertebrate" has been withdrawn in view of Applicant's cancellation of the claim in the amendment, filed 05/08/2008.

***Claim Rejections - 35 USC § 112 first paragraph***

5. The previous written description rejection under 35 U.S.C. 112, first paragraph for the recitation of **"parts of sPLA2 IIA"** has been withdrawn in view of Applicant's amendment to the claims, filed 05/08/2008.
6. The previous enablement rejection under 35 USC 112, first paragraph regarding "humanized vertebrates" has been withdrawn in view of Applicant's cancellation of the claims in the amendment, filed 05/08/2008.
7. The previous enablement rejection under 35 USC 112, first paragraph regarding "a pharmaceutical composition or a medicament" has been withdrawn in view of Applicant's cancellation of the claims in the amendment, filed 05/08/2008.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 27-33, 35-37 and 40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Mounier et al. (WO 98/55504, reference of record, see entire document) as evidenced by Touqui et al. (*Current Molecular Medicine* 2001, 1:739-754, reference of record, see entire document).

In response to Applicant's argument that the "hsPLA2 grll" taught by Mounier et al. is not another designation for sPLA2 IIA, Applicant is reminded that attorney argument cannot take the place of evidence in the record. *In re Schulze*, 145 USPQ 716, 718 (CCPA 1965). As noted in the previous Office Action, Touqui et al. states that "hsPLA2 grll" is synonymous with "sPLA2 IIA" as noted in the following section from Touqui et al.

It should be noted that the nomenclature of secretory PLA<sub>2</sub>s evolved since the discovery of these enzymes ten years ago, and different terms (sPLA<sub>2</sub>, synovial PLA<sub>2</sub>, snp-PLA<sub>2</sub>, **group-IIPLA<sub>2</sub>**, sPLA<sub>2</sub>-11) designating **sPLA<sub>2</sub>-IIA** can be found in the literature. (page 740, left column, first full paragraph)

It is also noted that the evidence Applicant relied upon by Kudo et al. does not appear to have been submitted; therefore it has not been considered.

In response to Applicant's argument that the prior art lacks enablement, it is noted that "the standard for enablement of a prior art reference for purposes of anticipation under section 102 differs from the enablement standard under 35 USC § 112" and that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." (See, *Impax Laboratories Inc.*, 81 U.S.P.Q.2d 1001, 1012, citing *Novo Nordisk Pharms., Inc v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005)).

Furthermore, Applicant has not provided any deficiency in the prior art teaching.

Attorney argument cannot take the place the evidence lacking in the record. *Meitzner v. Mindick*, 193 USPQ 17, 22 (CCPA 1977).

Applicant's arguments have been fully considered but are not found convincing essentially for the reasons of record set forth in the previous Office Action.

Therefore the rejection is maintained for the reasons of rejection as it applies to amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 27, 30, 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mounier et al. (WO 98/55504, cited on IDS) in view of Touqui et al. (*Current Molecular Medicine* 2001, 1:739-754) and Owens et al. (*Journal of Immunological Methods* 1994, 168:149-165).

Applicant's argument regarding Mounier et al. and Examiner's rebuttal are essentially the same as noted above.

Given that Mounier teach an antibody to sPLA2 IIA and the well-known technology of recombinant technology as taught by Owens et al., it would have been obvious to one of ordinary skill in the art to make a recombinant anti-sPLA2 IIA antibody that inhibits sPLA2 IIA upon reading the combined teaches of the prior art.

Applicant's arguments have been fully considered but are not found convincing essentially for the reasons of record set forth in the previous Office Action.

Therefore the rejection is maintained for the reasons of rejection as it applies to amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

### ***Conclusion***

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./  
Examiner, Art Unit 1644  
September 18, 2008

/Phillip Gambel/  
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September 24, 2008